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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/633,254      | 08/01/2003  | Douglas G. Evans     | 126688/0037         | 4792             |

7590

11/15/2005

Matthew W. Siegal  
Stroock & Stroock & Lavan LLP  
180 Maiden Lane  
New York, NY 10038

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/633,254

Applicant(s)

EVANS ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-116 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 16-23, 42 and 46-52 is/are allowed.
- 6) ☒ Claim(s) 5, 6, 14, 15, 24, 25, 39, 41, 43, 53-63, 65-74, 76-80, 82, 87, 88, 93-97, 99 and 106-116 is/are rejected.
- 7) ☒ Claim(s) 7-13, 26-38, 40, 44, 45, 64, 75, 81, 83-86, 89-92, 98, and 100-105 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/9/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

1. Claim 83 is objected to because of an informality, which can be corrected as follows: In line 4, the second occurrence of "second" should be replaced by -first--. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 5, 6, 14, 15, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Chamberlin (2,097,018). Chamberlin discloses, in the figures, a connector having a central portion, a first arm (6) or elongate base portion pivotally mounted to the central portion with first and second portions connected by a living hinge (7) and having a first opening (10) or first engaging structure, a second arm (5) or arm pivotally mounted to the central portion and having a first projection (11) or second engaging structure receivable in the first opening, and an attachment point (14) or implant attachment structure.
4. Claims 53-63, 65, 66, 72-74, 76-80, 82, 87, 93-97, and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhee (3,913,179). Rhee discloses, in the figures, an implant member or body and a method for its manufacture, where the member or

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body has a central portion with first and second sides and a constant width, first and second arm sections or first, second, and third sections or regions; where at least one of the first and second arm sections has an irregular border, where the central portion has smooth edges, where at least one of the central portion and first and second arms has a plurality of slits or openings or rectangular holes arranged in a pattern of parallel rows, and where the implant member is made of a shape-maintaining material.

5. Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Seitzinger (5,362,294). Seitzinger discloses, in figures 1-3, an introducer needle with a tubular body (20), a rod (22), and a needle tip (16 or 18) with a cavity.

6. Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Aldeen (2,427,176). Aldeen discloses, in figures 1-3, a needle-like device having a body portion with a curved portion (i.e., a cylindrical surface at 30), a flared section (31), and a flat spatulated section having an internal opening (34).

7. Claims 67-71 and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Gellman et al. (6,042,534). Gellman et al. disclose, in the figures and in col. 7, lines 24-50 and col. 10, lines 55-61, an implant member with a central portion (10 or 110) or support section and first and second arms (36 or 148) or first and second extension loop filaments, where the central portion is made of a first, natural material or dermal tissue (e.g., collagen), and the arms are made of a second, synthetic material or a synthetic mesh (fabric), and where the arms are joined to the central portion by a suture or ultrasonic bonding.

8. Claims 106-116 are rejected under 35 U.S.C. 102(b) as being anticipated by

Lehe et al. (6,273,852). Lehe et al. disclose, in the figures 4a-5h, a method of providing support for a female urethra as claimed, where the method includes application of an implant member (12), an introducer needle (10a), a handle (21), and a second needle (10b).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seitzinger in view of Lehe et al. Seitzinger discloses the invention substantially as claimed, but does not disclose a needle tip with at least one groove for receiving a filament. Lehe et al. teach, in figures 3a-3c, needles with at least one groove (at 20 or 40) for receiving a filament. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to include at least one groove for receiving a filament in the needle of Seitzinger's device. Such a groove would allow a convenient

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place for securing a filament to the needle and would allow accurate placement of a filament with a needle inserted in a patient's body.

***Allowable Subject Matter***

11. Claims 1-4, 16-23, 42, and 46-52 are allowed.
12. Claims 7-13, 26-38, 40, 44, 45, 64, 75, 81, 83-86, 89-92, 98, and 100-105 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
13. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a system for supporting a female urethra having an introducer needle with a flattened portion and an opening, a handle having a latch, an implant member, and a connector joining the implant member to the flattened portion of the needle; a connector with an implant attachment structure connected to an implant member by at least one of a suture, an adhesive, a press-connector, and a thermal process; a connector with a central portion having first and second engagement structures and first and second arms each with a tooth or third and fourth engagement structures or a first arm with a boss; a connector with, inter alia, first and second arms and the implant attachment structure has third and fourth arms; an introducer needle with, inter alia, first and second flat spatulated sections and a flared section connecting the first flat spatulated section to a central

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portion; an introducer needle with, inter alia, a tubular body with a lumen, a rod, needle tip movably disposed in the lumen, and a pushbutton connected to the rod; an introducer needle and a handle for the needle, where the needle has a body portion, a flared section, and flat spatulated section with a "T"-shaped or an "H"-shaped opening; an implant member with a flexible elongated body and a plurality of slits in first and second rows and a central portion that changes in width or is enlarged with respect to the rest of the body; an implant member with a slit ratio of approximately 1.5:1 and made of a natural material or acellular porcine dermal tissue; an implant member with first and second extension loop filaments and a support section with holes at first and second ends and first and second connectors joined to the filaments; a method of manufacturing an implant member, where a skin graft mesher is used to create slits in the body of implant member, where the body is tensioned to form holes from the slits; and the slits are in rows, and where the each slit is staggered with respect to a slit in adjacent row.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

### ***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo  
Primary Examiner

November 10, 2005